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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 901,484	07 09 2001	Daniel Cohen	GEN-T111XC3D2	6608

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
2421 N.W. 41ST STREET  
SUITE A-1  
GAINESVILLE, FL 326066669

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/901,484

Applicant(s)

COHEN ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-49 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement (PTO-144) (if filed)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other \_\_\_\_\_

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***Restriction/Election***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 9, 11-18, 38 (SEQ ID NO: 179) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- II. Claims 1-4, 9, 11-18 and 39-40 (SEQ ID NO: 3) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- III. Claims 1-4, 9, 11-18 and 40-41 (SEQ ID NO: 4) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- IV. Claims 1-4, 9 and 11-18 (SEQ ID NO: 69) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- V. Claims 1-4, 9 and 11-18 (SEQ ID NO: 112) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- VI. Claims 1-4, 9 and 11-18 (SEQ ID NO: 113) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- VII. Claims 1-4, 9 and 11-18 (SEQ ID NO: 114) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- VIII. Claims 1-4, 9 and 11-18 (SEQ ID NO: 115) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- IX. Claims 1-4, 9 and 11-18 (SEQ ID NO: 116) are drawn to a

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- X. Claims 1-4, 9 and 11-18 (SEQ ID NO: 117) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XI. Claims 1-4, 9 and 11-18 (SEQ ID NO: 118) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XII. Claims 1-4, 9 and 11-18 (SEQ ID NO: 119) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XIII. Claims 1-4, 9 and 11-18 (SEQ ID NO: 120) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XIV. Claims 1-4, 9 and 11-18 (SEQ ID NO: 121) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XV. Claims 1-4, 9 and 11-18 (SEQ ID NO: 122) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XVI. Claims 1-4, 9 and 11-18 (SEQ ID NO: 123) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XVI. Claims 1-4, 9 and 11-18 (SEQ ID NO: 124) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.
- XVII. Claims 1-4, 9 and 11-18 (SEQ ID NO: 182) are drawn to a recombinant, purified, or isolated polynucleotide, classified in class 536, subclass 23.1.

Invention XVII also encompasses SEQ ID NOS: 183-578 which have not been enumerated, however, if applicant elects Invention XVII any one of these sequences can be elected as it has been established on the record that

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- XVIII. Claims 5-8 are drawn to a purified or isolated polypeptide (SEQ ID NO: 4), classified in class 530, subclass 350.
- XIX. Claims 5-8 are drawn to a purified or isolated polypeptide (SEQ ID NO: 5), classified in class 530, subclass 350.
- XX. Claims 5-8 are drawn to a purified or isolated polypeptide (SEQ ID NO: 70), classified in class 530, subclass 350.
- XXI. Claims 5-8 are drawn to a purified or isolated polypeptide (SEQ ID NO: 74), classified in class 530, subclass 350.
- XXII. Claims 5-8 are drawn to a purified or isolated polypeptide (SEQ ID NO: 125), classified in class 530, subclass 350.

Invention XXII also encompasses SEQ ID NOS:125-136, which have not been enumerated, however, if applicant elects Invention XXII anyone of these sequences can be elected as it has been established on the record that claims 5-8 will be examined with the elected sequence. This is not a species election.

- XXIII. Claims 10 and 42 are drawn to an antibody, classified in class 530, subclass 387.1
- XXIV. Claims 19-21 are drawn to a method of determining whether an individual is at risk of developing cancer or prostate cancer, classified in class 435, subclass 6.
- XXV. Claims 22-23 are drawn to a method of obtaining an allele of the PG1 gene, classified in class 435, subclass 69.1.

XXXX. Claims 24-25 are drawn to a method of obtaining an allele of the PG1 gene, classified in class 435, subclass 69.1.

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XXVII. Claims 28-37 are drawn to methods of genotyping and detecting haplotype, classified in class 435, subclass 6.

XXVIII. Claims 43-49 are drawn to a computer readable medium, classified in class 435, subclass 283.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-XVII are patentably distinct polynucleotides, having different structure and function (see the sequence disclosure). Therefore, if any one of Inventions I-XVIII is elected, the claims will be examined only in-so-far as it pertains to the elected SEQ ID NO.

Inventions XVIII- XXII are patentably distinct polypeptides, having different structure and function (see the sequence disclosure). Therefore, if any one of Inventions XVIII-XXII is elected, the claims will be examined only in-so-far as it pertains to the elected SEQ ID NO.

The nucleic acids of Inventions I-XVII are related to the protein of and Inventions XVIII-XXII by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and

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protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Inventions I-XVII and the antibody of Invention XXIII are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The proteins of Inventions XVIII-XXII are related to the antibodies of Invention XXIII by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own

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identification of agonists or antagonists of the receptor protein.

The methods of Inventions XXIV-XXVII are patentably distinct as they use different products, have different method steps and end points.

Inventions I-XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Inventions I-XXIII and XXVIII can be used in a materially different process as the DNA can be used in a hybridization assay, the protein to make antibodies, the antibody can be used as a drug and the computer readable medium can be used in different bioassays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination



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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for

should you choose to fax your response. The faxing of such

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papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS *HR*  
Patent Examiner

*Karen Cochrane Carlson (cc 1001484)*

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER